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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,000	03/13/2001	Geert Jannes	2752-33	1152

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,000	JANNES ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-49* is/are pending in the application.

4a) Of the above claim(s) *37-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16 and 18-34* is/are rejected.

7)☒ Claim(s) *17,35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The petition under 37 CFR § 1.181(a) and MPEP 711.03(c) filed on July 1, 2005 to revive this case was granted because applicant never received the Office action mailed of July 27, 2004. Accordingly, prosecution is reopened.

Election/Restrictions

Claims 37-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions for reasons discussed in response to the renewed petition mailed June 18, 2004, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 24, 2002. Claims 13-36 are under consideration.

Information Disclosure Statement

The information disclosure statement filed March 13, 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, i.e. DE 197 16 456. It has been placed in the application file, but the information referred to therein has not been considered. The remaining references listed in the information disclosure statement were considered and an initialed copy was mailed to applicant September 10, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-16 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step in the claims is: a mechanism for detecting the products amplified by the primer mixture, which is the object of the preamble.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-16, 18-24 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jannes et al. (US 6,025,132), Claas et al. (Journal of Virological Methods. 1992; 39 (1-2) 1-13, abstract only), Paton et al. (Journal of Clinical Microbiology. 1992; 30 (4): 901-904, abstract only), Kinchington et al. (Investigative Ophthalmology and Visual Science. 1994; 35 (12): 4126-34, abstract only), Saikku et al. (Clinical Microbiol and Infect. 1997; 3 (6): 599-606), Gilbert et al. (Journal of Clinical Microbiology. 1996; 34 (1): 140-143), Fluitt et al. (WO 95/13396. May, 1995), and Echevarria et al. (Journal of Clinical Microbiology. May, 1998; 36 (5): 1388-1391). (Please note that all of these references were provided to Applicant in the correspondence mailed September 10, 2002, except for the Fluitt et al. WO reference, which is being forwarded with this action.)

The claims are drawn to a method of detecting acute respiratory tract infections in a sample by reverse transcription followed by simultaneous amplification of specific genes of various bacteria and viruses that may be present in the sample with at one primer set for each gene to be amplified. The amplified products are detected with a probe specific for each of the amplified products and immobilized on a solid support. The amplified products are also sequenced.

Saikku et al. teaches that respiratory tract infections are caused by influenza A and B, adenovirus, parainfluenza viruses, respiratory syncytial viruses, enteroviruses, *M. pneumonia*, and *C. pneumonia*, see Table 1 on page 599. Saikku et al. also teaches that nucleic acid detection methods to diagnose respiratory diseases provide sensitive and specific diagnosis within 24 hours, see the last paragraph before the "Treatment" section on page 602.

Saikku et al. does not teach simultaneous amplification of all of the nucleic acids from the pathogens that might be present in a sample or specific primers and probes to the specific regions claimed.

Gilbert et al. teaches simultaneous amplification and probe detection with several different primer sets of clinical samples by RT-PCR to determine whether a patient is infected with respiratory syncytial virus, parainfluenza virus, and picornaviruses, see the abstract and the materials and methods section. To determine whether a patient has PIV-3 or an enterovirus, Gilbert et al. amplifies the 5' non-coding region of the PIV-3 fusion protein gene and the 5' non-coding region of an enterovirus, see "RT-PCR" bridging columns on page 140. Gilbert et al. does not teach specifically detecting the regions for influenza virus A or B, hemagglutininneuraminidase gene for PIV-1, the F1 subunit of the fusion protein of RSV, or

detecting the instant regions for *M. pneumonia* and *C. pneumonia* or *B. pertusis* and *B. parapertusis*.

However, Claas et al. teaches detecting a PCR technique for simultaneous type-specific identification of influenza virus A and B using a combination of primer sets specific for the non-structural proteins of the viruses, see the abstract provided. This reference is admitted prior art on page 13, lines 14-25.

Paton et al. teaches specific detection of respiratory syncytial virus in clinical samples by PCR amplifying the F1 subunit of the fusion protein of RSV, see the abstract provided. This reference is admitted prior art on page 13, lines 14-25.

Echeverria et al. teaches the simultaneous PCR amplification and probe detection of clinical samples to determine if the sample contains PIV-1, PIV-2, or PIV-3 using a primer mixture and amplifies the hemagglutininneuraminidase gene for PIV-1, see the materials and methods section.

Kinchington et al. (Investigative Ophthalmology and Visual Science. 1994; 35 (12): 4126-34, abstract only) teaches specific amplification and probe detection of the adenovirus hexon gene in clinical samples using PCR, se the abstract provided.

Jannes et al. teach the simultaneous PCR amplification and probe detection of microorganisms in a respiratory tract infection sample, see claim 1. Jannes et al. also teaches specific primers and probes to amplify and detect the 16S rRNA sequence, the spacer region between the 16S and the 23S rRNA sequence of *M. pneumonia* and *C. pneumonia* and also teaches the specific detection of *B. pertusis* and *B. parapertusis*, see the table of column 13, column 18, lines 44-54, column 38, line 42 to column 40, line 22, and Example 6 in column 62.

Jannes et al. also teach detection of the target material by sequencing methods known in the art, see column 9, lines 51-55. Jannes et al. also teach immobilizing target amplified nucleic acids on a solid support in order to use mixtures of different probes that are differently labeled to obtain a different detection signal for each of the probes hybridized to the target, see column 10, line 66 to column 11, line 2.

One of ordinary skill in the art at the time the invention was made would have been motivated to simultaneously detect respiratory tract disease organisms and viruses to more quickly determine the pathologic cause of the disease to administer the proper treatment as soon as possible. Saikku et al. teaches that there are no symptoms that readily differentiate the pathogen causing the respiratory infection, see the last paragraph on page 600. Therefore, simultaneous detection of multiple organisms would eliminate improper diagnosis and treatment because specific identification of the pathogen(s) causing the infection would be known. One of ordinary skill in the art at the time the invention was made would have been further motivated to PCR amplify respiratory tract infections because the method is less time consuming than culturing swabs from the respiratory tract of an infected individual and because PCR is a more sensitive, specific and accurate detection technique. Gilbert et al. teaches that the PCR method had over 94% sensitivity for detecting the different viruses. One of ordinary skill in the art at the time the invention was made would have combined the specific primers and probes to amplify the instant regions taught by Claas et al., Jannes et al., Paton et al., Echeverria et al., Fluitt et al., Kinchington et al., and Gilbert et al. because each reference teaches a specific region unique to the virus or bacteria detected. This ensures that there is no mistaken identity for each of the products amplified and subsequently detected by a probe specific for each amplified product.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing combining the primers taught by the references to detect multiple respiratory tract pathogens because each of the references demonstrate that the specific primers and probes taught are highly specific for the pathogen to be amplified against control samples. Also, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for screening for multiple organisms taught because Jannes et al., Echeverria et al., and Gilbert et al. teach the simultaneous identification of various pathogens using multiplex PCR techniques and Gilbert et al. teaches that the PCR diagnostic panel is easily expanded to include other pathogens, see the discussion section on page 142, which would include the specific primers and probes of Claas et al., Paton et al., Jannes et al., Fluitt et al., and Kinchington et al. to readily differentiate the pathogen causing the respiratory infection taught by Saikku et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 25-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Jannes et al., Claas et al., Paton et al., Kinchington et al., Saikku et al., Gilbert et al., Fluitt et al., and Echevarria et al. as applied to claims 13-16, 18-24 and 29-34 above, and further in view of Fluitt et al. (WO 95/13396. May, 1995; GenEmbl Accession No: A44457), Jannes et al. (WO 96/00298. January, 1996; GenEmbl Accession No: A47982). Both of these references were provided in the correspondence mailed September 10, 2002.

See the teachings of Jannes et al., Claas et al., Paton et al., Kinchington et al., Saikku et al., Gilbert et al. and Echevarria et al. None of the references teach any of the sequences disclosed in claims 25-28.

However, SEQ ID NO: 15 and 18 are taught by Fluitt et al. and Jannes et al. WO 96/00298, respectively, see the previous sequence alignments provided.

One of ordinary skill in the art at the time the invention was made would have used the conventional sequence probes of Fluitt et al. and/or Jannes et al. to detect and identify the specific amplified products in the sample with a reasonable expectation of success, absent unexpected results to the contrary.

Allowable Subject Matter

Claims 17, 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach or suggest the primer pairs recited for each of the pathogens in claim 17, i.e., SEQ ID NOs: 17-21 and 35-52.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Primary Examiner
Art Unit 1648